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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,116	09/26/2001	Ekambar R. Kandimalla	HYZ-479CP (47508.577)	3956
32254	7590	04/18/2005	EXAMINER	
KEOWN & ASSOCIATES 500 WEST CUMMINGS PARK SUITE 1200 WOBBURN, MA 01801			LE, EMILY M	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/965,116

Applicant(s)

KANDIMALLA ET AL.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2004 and 21 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-8 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-8 and 39-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 4-5 and 9-38 are cancelled. Claims 39-43 are added. Claims 1-3, 6-8 and 39-43 are pending and under examination.

### ***Change of Address***

2. Applicant's change of address/power of attorney is noted.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 (in part), 7-8 and 42 remain rejected under 35 U.S.C. 102(a) as being anticipated by Schwartz.

Applicant submits that Schwartz does not anticipate the claim as instantly presented because Schwartz describes modification of cytosine with a halogen group.

Applicant's submission has been considered, however, it is not found persuasive. In the instant, Schwartz continues to anticipate the claimed invention. Schwartz teaches immunomodulatory oligonucleotide that comprises a central CG sequence, wherein C is a modified cytosine. The modified cytosine Schwartz teaches includes cytosine arabinoside. Schwartz teaches the same oligonucleotide that is instantly claimed. Ergo, Schwartz anticipates the claimed invention.

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5. Claims 1-3 (in part), 7 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Zuo et al.

Applicant submits that Zuo et al. does not anticipate the claimed invention because Zuo et al. does not deal with immunostimulatory oligonucleotides or their administration, with emphasis added to immunostimulatory.

Applicant's above submission has been considered, however, it is not found persuasive. MPEP § 2112 states, "something which is old does not become patentable upon the discovery of a new property". In the instant, Zuo et al. teaches the claimed oligonucleotide. Zuo et al. teaches of an oligonucleotide that comprises the CG sequence, wherein C is a modified cytosine. The modified cytosine Zuo teaches includes 5-hydroxymethylcytidine—a 5-hydroxymethylcytosine attached to a sugar group.

Since the oligonucleotide of Zuo et al. is the same as the claimed invention, any description of properties made by Applicant would be an inherent property of the composition of Zuo et al. Ergo, the oligonucleotide of Zuo et al. would inherently be immunostimulating. Thus, Zuo et al. anticipates the claimed invention.

6. Claims 1-3 (in part), 7 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Butkus et al.

The claims limit the unnatural pyrimidine to N4-alkylcytosine.

Butkus et al. teaches a CpG composition that comprises an unnatural pyrimidine, wherein the unnatural pyrimidine is N4-methylcytosine. N4-methylcytosine is an N4-

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alkylcytosine. The CpG composition of Butkus et al. is the same as the claimed invention. Ergo, Butkus et al. anticipates the claimed invention.

7. Claims 1-3 (in part), 6-7 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Kreutzer et al.

The claims limit the unnatural pyrimidine to 5-hydroxymethylcytosine.

Kreutzer et al. teaches a CpG composition that comprises an unnatural pyrimidine, wherein the unnatural pyrimidine is 5-hydroxymethylcytosine. The CpG composition of Kreutzer et al. is the same as the claimed invention. Ergo, Kreutzer et al. anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz in view of Bennett et al.

The claims limit the unnatural pyrimidine 4-thiouracil.

Schwartz teaches immunomodulatory oligonucleotide that comprises a central CG sequence, wherein C is a modified cytosine.

Schwartz does not teach the use of 4-thiouracil as a modified cytosine, a pyrimidine. However, Schwartz teaches that any other modified pyrimidine can be used

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in place of the modified cytosine that Schwartz teaches to make an immunomodulatory oligonucleotide.

Bennett et al. teaches a comprehensive listing of modified pyrimidine bases, including 4-thiouracil, that can be used in place of the natural pyrimidine base.

In view of the teachings of Schwartz and Bennett et al., it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to substitute known equivalents with one another. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because Schwartz suggests the use of modified pyrimidine in an immunomodulatory oligonucleotide and 4-thiouracil is a modified pyrimidine.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

### ***Conclusion***

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

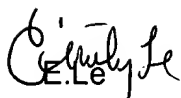
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Emily Le



Jeffrey S. Parkin, Ph.D.  
Primary Patent Examiner  
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